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Subject: Environmental Defense comments on 2,4,8,10-Tetraoxa-3,9-diphosphaspiro[5,5]undecane, 3,9-bis(octadecyloxy)-

(Submitted via Internet 6/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and mark_Thomson@cromptoncorp.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 2,4,8,10-Tetraoxa-3,9-diphosphaspiro[5,5]undecane, 3,9-bis(octadecyloxy)-(CAS# 3806-34-6), also known as O,O'-dioctadecylpentaerythritol bis(phosphite) and commercially as Weston 618. [Note that the heading of Table 1 in the test plan lists an incorrect CAS# 10081-67-1, which corresponds to the substance evaluated in an earlier Crompton submission.]

The test plan and robust summaries for Weston 618 were submitted by Crompton Corporation. This substance, according to the test plan, is used as a color and molecular weight stabilizer for polyolefins, polyesters, elastomers, engineering thermoplastics and adhesive formulations. No information was provided regarding its synthesis, potential for environmental releases or opportunities for human exposure. In general, the test plan and robust summaries meet minimum standards for the HPV Program.

The sponsor proposes to conduct a combined reproductive/developmental toxicity study on Weston 618 and also a hydrolysis study, as there are no available data on these SIDS endpoints. We agree with this proposal and we also recommend that the sponsor conduct a water solubility study and fish toxicity study. The solubility was estimated from a model, as were all the ecotoxicity data. The test plan states that the ECOSAR estimates for the three ecological toxicity endpoints are greater than the estimated limit of solubility, so meaningful tests would not be possible. Perhaps this is true, but the ECOSAR models, although useful, can grossly over or underestimate toxicity under some circumstances. Weston 618 is not readily biodegradable, so it may enter the environment from the array of manufacturing and consumer applications. Therefore, some actual experimental data should be obtained to validate the model predictions. We recommend that the sponsor conduct at least a fish toxicity study on Weston 618 and, depending on the results, aquatic invertebrate and algal toxicity studies should be considered.

Other comments are as follows:

1. Weston 618 is the commercially-used substance and we agree with the sponsor that it should be used instead of the pure chemical in toxicity studies. However, the sponsor does need to indicate the composition, including concentrations of contaminants, in the commercial material.

2. Available data from repeat dose, genetic toxicity and acute toxicity studies indicate a very low order of mammalian toxicity. There seems to be no hallmark target organ for Weston 618.

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3. The robust summary describing the rat repeat dose study states that lesions of the trachea and lungs were observed in both control and treated rats that were suggestive of chronic murine pneumonia. The sponsor needs to provide more information on the possible consequences of this finding in order to claim that this study is indeed valid.

Thank you for this opportunity to comment.

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